

US EPA ARCHIVE DOCUMENT



NAFTA Technical Working Group on Pesticides  
Grupo de Trabajo Técnico del TLCAN sobre Plaguicidas  
Le groupe de travail technique de l'ALENA sur les pesticides

# Biopesticides Registration Improvement Course

## Electronic Submission



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Office of Pesticide Programs

Information Technology and Resource Management  
Division



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## Agenda

- Current e-Label effort
- Background and update on OPP's current e-Submission efforts
  - Methods of creating electronic submission packages
  - e-Dossier Builder pilot project
- Future direction of OPP's electronic submission
  - International harmonization of e-submission standard
  - Advancing to web technologies
- Future use of structured content

# Many sides to Electronic Pesticide Registration

## Application

- ✓ Fill/print .PDF forms
- ✓ Text .PDF labels
- ✓ E-CSF builder
- ✓ XML application structure

- XML study summary
- XML application builder
- XML structured label

## Transmission

- ✓ Courier CD w/ text .PDF label + paper application
- ✓ Courier CD w/ XML application (no paper)

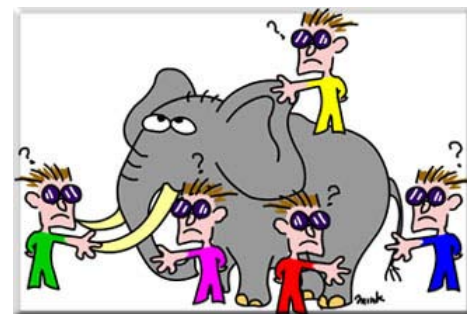
- Send electronically to EPA
- Electronic signatures

## Distribution

- ✓ image of stamped label (.TIFF, .PDF)
- ✓ OCR image to text .PDF

- Electronically stamp label
- Web Distributed Labeling

- ✓ available now
- future





# e-Labels (Current)



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## Why e-Labels?

- Text .PDF label facilitates EPA review
- COMPARE - proposed label to last version to quickly identify changes
- COMMENT - mark any needed revisions and return to registrant for corrections





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### How to create an e-label

Using Adobe Acrobat Professional v 8 (Acrobat Distiller)\*      \* or can use any PDF creator

- In any application, hit “File”>“Print”
- Under “Printer Name”, select “Adobe PDF”.
- Next to “Printer Name”, select “Properties” and check the desired settings.
  - minimum: use "Standard" settings
  - better: use "EPA Label Print" (see website)
  - always uncheck "rely on system fonts..."
- Hit “OK”.
- Save PDF using EPA filename format.



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## Critical e-Label specifications

- Text .PDF (not scanned image)
- Embed all fonts used
- Follow file name syntax:
  - Reg#.yyyymmdd.anything else.PDF
  - Example:
    - 090898-00012.20100401.container disposal.pdf
- Use clean label without markups
- Full details on web –
  - <http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm>



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## File Name Specs

- registration #.yyyymmddsub-date.optional-id.PDF
  - registration # = EPA registration number with dash [6-5 digits]
  - Yyyyymmdd = date submitted (from 8570-1), YEAR FIRST
  - sub-date = optional version identifier (use letters b,c,d)  
if needed to distinguish versions on same date
  - optional-id = optional any other text or codes
  - .PDF = mandatory file extension
- note: USE LEADING ZEROS in registration # and date fields
- examples:
  - 000123-00859.20110512.PDF
  - 123456-12345.20100919b.celery.PDF



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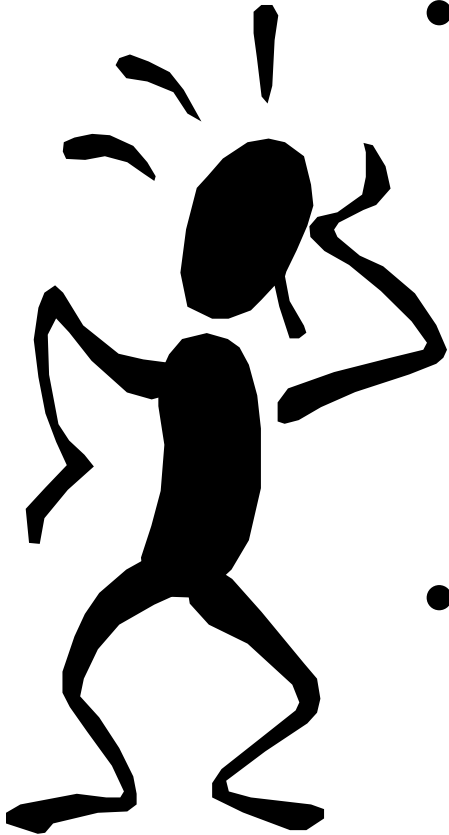
## Submitting e-Labels

- Initial application (new product, amendment, notification)
  - Paper application:
    - e-label .pdf on CD or DVD
    - include signed affidavit: electronic = paper (form on website)
  - E-submission:
    - e-label .pdf in XML package on CD or DVD
- Corrections (label resubmission)
  - Email:
    - response to EPA corrections can be emailed directly to staffer
- Include e-label with paper or electronic submissions!



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### Common Errors



- File name not correct
  - Don't forget periods after reg# and date
    - syntax and **periods** are used to automatically create label database record
  - Reg#.yyyymmdd.anything else.PDF
- CD or DVD unreadable
  - Remember to “**finalize**” or “**close**” disc so it is readable on other computers



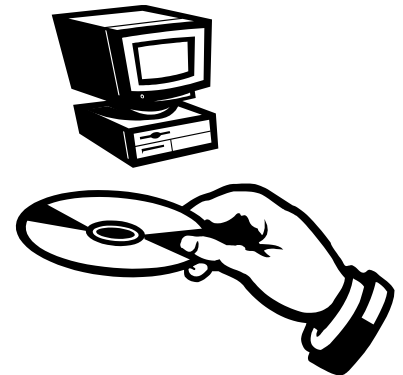
# e-Submission current effort



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## e-Submission: Status

- Initiated July 2008
- Continuing with limited regulatory types
  - Section 3 registrations: New & amendments
  - EUPs: New & amendments
  - New tolerance petitions
  - Distributor products
- 6(a)(2) Study submissions
  - Related to a product
  - Recently added capability
- Submission on CD/DVD via courier





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## e-Submission Statistics

Calendar year	Package count	Approx. percent of eligible submissions	Average number of documents	Percent of studies	Average process time (days)
2008*	108	3.5%	14	11.5%	1.5
2009	228	3.4%	11	12.8%	2.9
2010	424	6.1%	15	30%	2.6
2011**	71	5.5%	7	4%	1.7

\* 2008 from July 4

\*\* 2011 as of March 25



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## e-Submission Package Creation

- Guidance online at
  - <http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm>
- Key points
  - Pre-assignment of MRIDs
  - PRN 86-5 formatting applies
  - Entire submission electronic ☞ no paper!
  - Follow-up to paper submissions allowable
  - Replacement documents require special handling





## e-Submission Package Creation

- “Hand edit” method
  - XML based on Canada’s PMRA e-Index specification
    - Added 13 additional data fields
    - PMRA’s e-Index application a good starting point
    - MS Wordpad, MS XML Notepad, or other XML editor
- Automated creation using existing data systems
  - Modifications to in-house systems





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## e-Submission Package Creation

- e-Dossier Builder method
  - Pilot announced at PPDC Process Improvement Workgroup - December 2010
  - Some involvement but limited feedback
  - Plan to move forward with public distribution
  - Full implementation requires further internal modifications
    - Additional application types
    - Direct consumption of e-Dossier packages
  - “Invisible” package format standard
    - Differs from advertised specs





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## e-Submission Package Content

- All “documents” supporting the submission
  - Forms
  - Labels
  - Studies
- Study summaries
  - MS Word (current submission format) \*
  - [http://www.epa.gov/pesticides/regulating/studyprofile\\_templates/index.htm](http://www.epa.gov/pesticides/regulating/studyprofile_templates/index.htm)
- Supplemental Study Data
  - MS Excel or SAS transport
  - Long term toxicity studies
  - Environmental studies under consideration



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## Common Problems

- Files not zipped
- File name in xml not matching actual file name
- Not naming the enclosed files
- Blank disk or disk not closed
- Root MRID used across zip packages
- Missing required values in xml
- Multiple applications in single package





## Study Summaries

- **Question:** Consider as studies?  
MRID needed?
  - If simple summary of the original study
    - reference original study MRID in xml
    - identify as “study profile” (STP) in xml
  - If summary adds additional info
    - requires new MRID
    - identify as “study” (ST) in xml
  - If summary of multiple studies
    - requires own MRID
    - identify as “study” (ST) in xml





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## Replacement e-Documents

- Require special handling
  - PR Notice 86-5 rejections
  - “Typographical” corrections
    - only replacement file is needed
    - always send in on disk
    - additional email is ok if no CBI
    - use exact original file name





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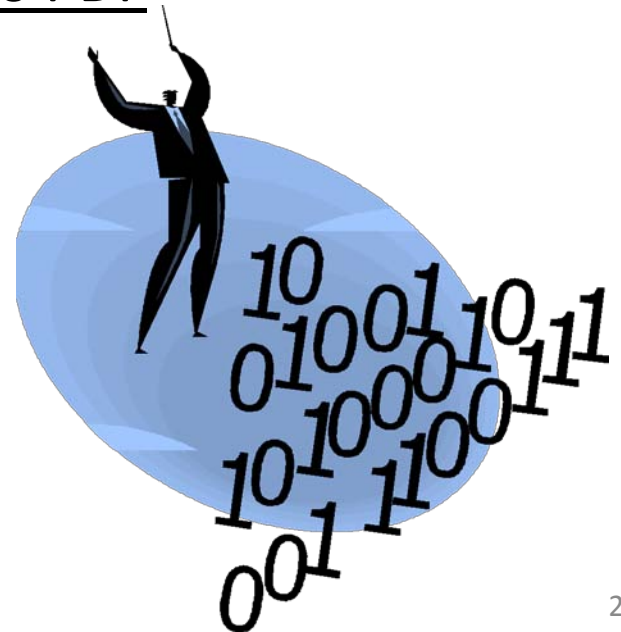
## Submitting Amended Studies

- **Question:** Reuse MRID or assign new MRID?
  - Typos can just be replacement versions
    - see replacement e-documents slide
  - If change in “science” then new MRID
    - some typos may be in this category
      - e.g. ppm vs. ppb or 12.3 vs 1.23
  - Grey area exists – still under consideration



## File Formats and Naming

- PDF
  - Studies, Forms, Labels, Correspondence, etc.
- MS Word
  - Simple study summaries
  - MRID'd study summaries in addition to PDF
  - Notice of Filing (tolerance petitions)
- MS Excel for raw data
  - Some specifications exist
  - Others under development
- File names
  - Labels
  - “e-PRISM” xml file





# Future direction of OPP's electronic submission



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## OECD Global Harmonized Submission Transport Standard (GHSTS)

- Pesticides regulatory process currently document based
- GHSTS is a “packaging standard” for electronic pesticide submissions
- Supports both centralized IT systems and stand-alone users (e.g. CADDY)
- Apparent move toward discrete data
  - Study summaries – currently available option
  - Label, forms – future potential
  - Still consistent with GHSTS
- Does not harmonize content
- Version 1 by fall 2011
  - Implementation longer due to IT modifications



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## OECD Study Summaries

- Standard data format for reporting chemical study summaries (XML)
- Prescribe formats to enter/maintain information in databases
- Aimed at developers of database systems
  - XML schema and schematron
- Content based on pesticide DERs
- Implementation to be consistent with OPP business strategy



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## Internet portal

- Secure Internet site for electronic submission
  - “Turbo Tax” like wizards
  - Individual File uploads
  - “ftp” for pre-made packages
  - Security through EPA Central Data eXchange
  - Bidirectional communication with registrants
    - Status tracking/updates
    - Documents





# Future use of structured content



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## Electronic Labeling

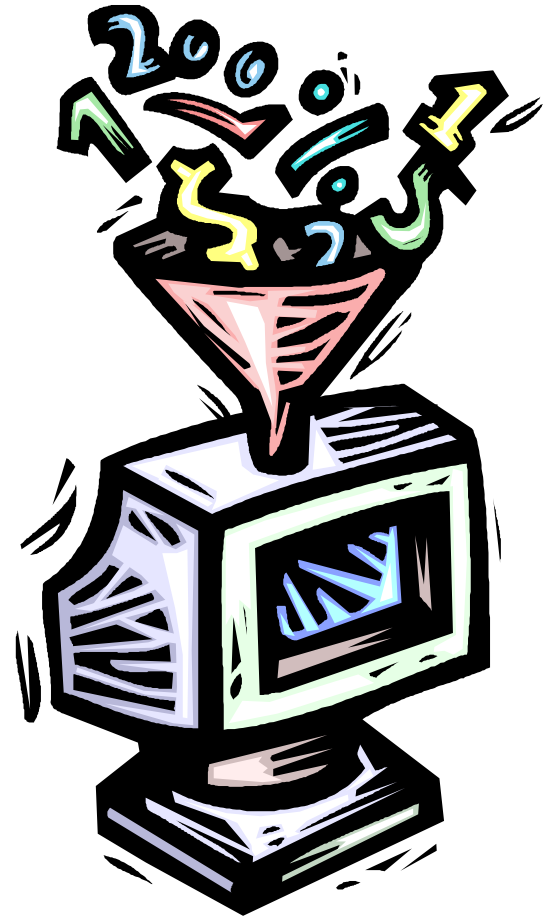
- PDFs currently encouraged
  - Include in paper or electronic submissions
- Evaluating structured label content as the submission format
  - Consistent with apparent OPP direction
  - Tools for label creation being considered
  - Efficiencies to OPP as well as registrants
  - Possible process changes



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## Other Structured Content

- Study summaries (DERs)
- Forms
- Confidential Statement of Formula (CSF)
- Supplemental study data
  - raw data





# Questions/Contacts

- Labels
  - Tom Harris
    - (703) 308-9423
    - [harris.thomas@epa.gov](mailto:harris.thomas@epa.gov)
- MRIDs, study formatting, etc.
  - Teresa Downs
    - (703) 305-5363
    - [downs.teresa@epa.gov](mailto:downs.teresa@epa.gov)
- E-Submission technical and e-Dossier pilot
  - Bob Schultz
    - (703) 308-8186
    - [Schultz.robert@epa.gov](mailto:Schultz.robert@epa.gov)